NHS
Bedfordshire, Luton and Milton Keynes
Integrated Care Board

Artificial Intelligence Policy

Document Status:

This is a controlled document. Any printed or downloaded copies are not controlled. The version of this document published on the Bedfordshire, Luton & Milton Keynes Integrated Care Board website is the controlled copy
www.befordshirelutonandmiltonkeynes.icb.nhs.uk

Sustainable Development - Environmental

Do you really need to print this document?

Please consider the environment before you print this document and where possible copies should be printed double-sided. Please also consider setting the page range in the print properties, when relevant to do so, to avoid printing the document in its entirety.

Document Control	
Document Owner:	Chief Medical Officer
Document Author(s):	Chief Digital and Information Officer
Directorate:	Chief Medical Directorate
Approved By:	Operational Group
Date of Approval:	06-01-2025
Date of Next Review:	06-01-2027
Effective Date:	06-01-2025

Version Control			
Version	**Date**	**Reviewer(s)**	**Revision Description**
Draft v0.1	10-2024	Mark Thomas	Initial draft
Draft v0.2	10-2024	Mark Thomas	Feedback received and updated
Draft v0.3	11-2024	Mark Thomas	Group feedback received and updates / revisions
Draft v0.4	12-2024	Mark Thomas	Additional feedback received, updated
Final v1.0	06-01-2025	Operational Group	Approved by Operational Group

Implementation Plan

Development and Consultation:	The following individuals were consulted and involved in the development of this document: ▪ Chief Medical Director ▪ Deputy Medical Director / Caldicott Guardian ▪ Chief Digital Information Officer ▪ Deputy Chief Digital Information Officer ▪ Head of Safe Practice (Digital) ▪ Head of Digital Delivery ▪ Deputy Chief Finance Officer ▪ Director of Contracting ▪ Deputy Peoples Director ▪ Head of BI & A ▪ Head of Innovation ▪ Head of Research
Dissemination:	Staff can access this document via the website and will be notified of new / revised versions via the staff briefing. This document will be included in the organisation's Publication Scheme in compliance with the Freedom of Information Act 2000.
Training:	The following training will be provided to make sure compliance with this document is understood: ▪ BLMK Statutory and Mandatory Training
Monitoring:	Monitoring and compliance of this document will be carried out via: Inclusion in DPIA for programmes utilising AI services
Review:	The Document Owner will ensure this document is reviewed in accordance with the review date on page 2.
Equality, Diversity and Privacy:	Appendix 1 - Equality Impact Assessment Appendix 2 - Data Protection Impact Assessment

Associated Documents:	The following documents must be read in conjunction with this document: ▪ BLMK HCP Digital Strategy
References:	The following articles were accessed and used to inform the development of this document: • Information Commissioner's Office – Artificial Intelligence Toolkit and associated documentation • NHS England • Health Research Authority • GOV.UK Understanding Artificial Intelligence Ethics & Safety • UK General Data Protection Regulation • Data Protection Act 2018 • The Common Law Duty of Confidentiality • Privacy and Electronic Communications Regulations • Confidentiality: NHS Code of Practice (Department of Health) • Human Rights Act 2000 • Caldicott Principles

Table of Contents

1.0 Introduction

1.1 NHS Bedfordshire, Luton and Milton Keynes Integrated Care Board (ICB) aims to ensure robust governance through its formal written procedural documents, such as this document, which communicate standard organisational ways of working. These documents help clarify operational requirements and consistency within day-to-day practice. They can improve the quality of work, increase the successful achievement of objectives and support patient safety, quality and experience. The ICB aims to ensure its procedural documents are user friendly, up-to-date and easily accessible.

1.2 The ICB must design and implement procedural documents that meet the diverse needs of our service and workforce, ensuring that none is placed at a disadvantage over others, in accordance with the Equality Act 2010. The Equality Impact Assessment initial screening, which was used to determine the potential impact this policy might have with respect to the individual protected characteristics is incorporated at Appendix 1.

1.3 A Data Protection Impact Assessment is a process which helps assess privacy risks to individuals in the collection, use and disclosure of personal information. The Data Protection Impact Assessment initial screening, which was used to determine the potential impact this policy might have with respect to an individual's privacy is incorporated at Appendix 2.

1.4 In the rapidly evolving field of health and care provision, the integration of artificial intelligence (AI) technologies has the potential to revolutionise resident care, streamline administrative processes, and enhance overall operational efficiency. BLMK ICB recognises the importance of adopting AI technologies while ensuring their ethical and responsible use. This AI policy serves as a guiding framework to ensure the appropriate deployment, management, and oversight of AI systems across the BLMK partners.

1.5 The ICB also recognises the role of AI in supporting research and innovation. AI-enabled research offers new opportunities for discovery, personalised care, and predictive analysis, all of which have the potential to improve patient outcomes and operational efficiencies.

2.0 Scope

2.1 The policy applies to Bedfordshire Luton and Milton Keynes ICB and all its employees and must be followed by all those who work for the organisation, including those on temporary or honorary contracts or secondment. It applies to all departments and services that utilise AI irrespective of their scale or scope. It applies to both internally developed AI systems and those procured from external suppliers.

2.2 This policy also extends to all AI-based research initiatives conducted within the NHS or in collaboration with external research partners. External researchers accessing NHS data for AI-related research must comply with Health Research Authority (HRA) guidance and ethics approval processes.

3.0 Definitions

Artificial Intelligence (AI) and Generative Artificial Intelligence - The theory and development of computer systems able to perform tasks normally requiring human intelligence, such as visual perception, speech recognition, decision-making, and translation between languages. For example: a language translator will, when using AI, produce an output which is naturally spoken or written and indistinguishable from someone who speaks it as a first language. Generative AI is a subset of AI referring to an intelligent machine that can learn from inputted data or its knowledge and by looking for apparent commonalities in the data produces new linked or completely unique information or data.

Data Protection Impact Assessments - A Data Protection Impact Assessment (DPIA) is a process to help identify and minimise the data protection risks of a project. The ICB requires that DPIAs are considered and where necessary completed in full for any new data processing activities, new systems, services, and commissioning activities. The Information Governance (IG) Team will review and approve DPIAs and advise of requirements and recommended actions as necessary.

Digital Technology Assessment Criteria (DTAC) - Developed by the NHS, the DTAC is a criterion required during the commissioning of digital health technologies across the NHS and social care services to ensure they meet the baseline minimum standards in multiple areas. The DTAC includes criteria covering clinical safety, data protection, technical security, interoperability, plus usability and accessibility. For your digital health product to pass the DTAC, you need to meet all requirements in each of the areas.

Machine Learning – is a sub-field of AI. It is the use and development of computer systems that are able to learn and adapt without following explicit instructions, by using algorithms and statistical models to analyse and draw inferences from patterns in data. Machine learning algorithms are trained on data sets to create models that enable machines to perform tasks that would otherwise only be possible for humans. These tasks include categorising images, analysing data, predicting price fluctuations etc.

Natural Language Processing – refers to the branch of computer science/AI concerned with giving computers the ability to understand text and spoken words in much the same way human beings can.

Processing - in relation to information or data means; obtaining, recording or holding the information or data or carrying out any operation or set of operations on the information or data, which may include adaptation or alteration of the information; retrieval, or use of the information or data; disclosure of the information or data by transmission, dissemination or otherwise making available, or alignment, combination, blocking, erasure or destruction of the information or data. In summary anything you do with data is “processing”.

Robotic Process Automation (RPA) - is a form of business process automation that uses automation technologies to mimic back-office tasks of human workers, such as extracting data, filling in forms, moving files, etc. By deploying scripts that emulate human processes, RPA tools autonomously execute various activities and transactions across unrelated

software systems. This form of automation uses rule-based software to perform business process activities at a high volume, freeing up human resources to prioritise more complex tasks. While RPA is sometimes mistaken for artificial intelligence (AI), the two are distinctly different, RPA is process-driven, whereas AI is data-driven. RPA bots can only follow the processes defined by an end user, while AI bots use machine learning to recognise patterns in data and learn over time, RPA and AI can complement each other well.

Research-Driven AI: AI used to identify patterns, support decision-making, and predict outcomes within clinical research and innovation.

Federated Learning: A machine learning approach that trains algorithms across multiple decentralised devices or servers, promoting data privacy and security.

Synthetic Data: Artificially generated data that mimics real data but does not include real patient information, used to train AI models without privacy risks.

4.0 Policy Statement

4.1 The ICB is committed to the ethical and transparent use of AI in research, clinical, and administrative settings. AI must be used in ways that are fair, accountable, and protective of individuals data and rights.

AI initiatives that support research and innovation must align with NHS research objectives. All research-driven AI activities must adhere to ethical standards, ensure fairness, and protect individuals rights.

5.0 Roles and Responsibilities

5.1 The following have specific responsibilities in relation to this policy.

Senior Information Risk Owner (SIRO):

- Take responsibility for the overall governance and management of information risks associated with AI systems.
- Ensure that appropriate risk management processes, controls, and policies are in place.
- Collaborate with other stakeholders to address potential risks and mitigate any adverse impacts arising from AI implementation.
- Provide oversight and strategic direction to ensure the responsible use of AI technologies.

Caldicott Guardian (CG):

- Ensure data is processed in accordance with the Caldicott Principles
- Ensure confidential patient information is processed legally, ethically and appropriately.
- Provide advice and guidance to staff on the implementation of AI.

Head of Safe Practice (Digital):

- Oversee and ensure compliance with data protection regulations and best practice associated with AI.
- Provide guidance on data privacy related to AI systems.
- Review & approve Data Protection Impact Assessments (DPIAs) for AI projects.
- Serve as the point of contact for data subjects and supervisory authorities regarding data protection concerns related to AI.

Senior Information Governance lead / IG Manager:

- Review and approve Data Protection Impact Assessments for all AI projects.
- Serve as a point of contact for staff with queries or concerns relating to AI.
- Provide guidance relating to data protection and AI.
- Ensure the implementation of AI is in line with data protection legislation.

Clinical Safety Officer:

- Assess the safety risks associated with AI systems used in clinical settings.
- Collaborate with relevant stakeholders to establish safety protocols and guidelines for AI implementation.
- Monitor and evaluate the performance and safety of AI systems.
- Investigate and address any incidents or concerns related to the clinical safety of AI systems.

Business Intelligence and Intelligence Staff:

- Assist in the implementation, integration, and maintenance of AI systems.
- Ensure the proper configuration, security, and compatibility of AI systems with existing IT infrastructure/service provision.
- Collaborate with vendors and other stakeholders to address technical issues and provide technical support for AI systems as required.

Finance & Procurement Teams:

- Finance & Procurement Teams have an obligation to make the Senior Information Governance Manager aware of any requests to implement AI software.
- Requests for AI solutions will be assessed and authorised by the Information Governance and IT Teams. A Data Protection Impact Assessment **MUST** be completed prior to implementation; this is a legal requirement for AI.

Research and Innovation:

- Provides guidance to researchers on obtaining regulatory approvals and completing DPIAs for research initiatives.
- Assist researchers by signposting them to the correct Health Research Authority (HRA) guidance and advising them on how to apply for ethics approval.
- Facilitates exploration, adoption, and scaling of AI innovations that support research and innovation objectives.

- Engages in collaborative partnerships with academia, industry and health and social care providers to create added value to address local needs, accelerate innovation and involvement in research involving AI and data.

Head of Organisational Development:

- Support the lead manager in any change management programmes relating to AI including undertaking a people impact assessment, staff/ trade union engagement or consultation.
- Develop the workforce to have the skills and confidence they need to make the most of digital services and improve care, through access and signposting to appropriate raining programmes

Employees & Authorised users:

- Familiarise themselves with and adhere to the ICB's Information Governance & Security policies, protocols and guidelines including remaining up to date with Mandatory IG/Data Security Training.
- Report any concerns or issues related to the AI systems to the the IG Team via blmkicb.ig@nhs.net

Audit & Risk Assurance Committee:

To ensure compliance with the policy as required

6.0 Processes and Procedures

6.1 Defining the purpose and identifying a legal basis for the use of AI:

Generative artificial intelligence can be used in many ways to enhance the work of the ICB**.**

It is important that the purpose and use of AI is clearly defined and agreed, including why AI is being used, the intended benefits and what measures / metrics will be monitored in order to demonstrate impact / the value it will bring to the organisation. You must also determine if a legal basis for the use of data is required before any data is processed. Where possible any data should be anonymous so a legal basis would not be required. However, it is important that data and use cases are carefully assessed to determine if individuals can be identified using the contents of the information even if common identifiers such as name, address and phone number are removed. The combined details of a local area, a rare disease and a very young age may enable a patient to be identified. In such cases you would need to treat this as personal data and therefore identify a legal basis for the processing along with meeting the requirements of the common law duty of confidentiality.

The above requirements also apply to data used to test and develop AI systems even if there is no outcome or decision for an individual, this is because you are processing data by using it to train AI models or algorithms.

In general, AI can be used in healthcare in four ways:

- AI specifically for use in healthcare settings,
- AI for population or health research,
- Freely or commercially available 'generic' AI products.
- Individual productivity

How these should be used in health and care settings is outlined below.

Developing Artificial Intelligence Products for Healthcare

The NHS's AI and Digital Regulations Service is an AI regulation service for people who develop or plan to use AI or a digital technology in health and social care. It brings together regulations, guidance and resources for digital healthcare technologies. The service is comprised of four partners;National Institute for Health & Care Excellence (NICE), Medicines and Healthcare products Regulatory Service (MHRA), Health Research Authority (HRA) and Care Quality Commission (CQC). You can contact this service at: Regulations and guidance for developers - AI and Digital Regulations Service for health and social care (innovation.nhs.uk)

Using AI for Research

Health Research Authority (HRA) approval is required for research studies that take place in the NHS in England and Wales. The HRA AI and Digital Regulations Service' can provide guidance for NHS AI adopters, and digital health innovators.

Review by an NHS Research Ethics Committee (REC) is required, as well as an assessment of regulatory compliance and related matters undertaken by dedicated HRA staff.

If you are planning to develop an AI research programme within the NHS, the Research and Innovation function will be able to provide advice and guidance on how to apply for research ethics and approvals via the Health Research Authority.

Defining Purpose and Legal Basis for Research AI

- AI research must have a clearly defined purpose which aligns with NHS Long-term plan and objectives outlined within the document
- Data should be anonymised wherever possible.
- AI models must be validated for "fit for research use".

- Data used for AI model training must be assessed for potential bias.

Reporting and Transparency

Maintain a public register of AI research initiatives.

Any concerns about AI systems in research must be reported via Datix.

Freely Available Artificial Intelligence Apps and Services

AI is a feature of many applications currently used by staff including smart technology enabled applications (Apps) within MS Teams or other Microsoft Office products. It is important to use AI appropriately and responsibly to ensure that it does not compromise personal data, business sensitive information, violate policies, or pose a risk to patient safety or our network integrity. The ICB recommends caution when using freely available AI software such as Chat GPT. Although it can be used in the same way you might use different sources to kickstart a research project or better understand what people are saying about a topic, it should not be used as your primary source for information because it can produce inaccurate, biased or false information.

The UK's National Cyber Security Council (NCSC) states that you should not enter sensitive information (such as personal details or company intellectual property) into chatbots, and not to perform queries that could be problematic if made public (for example sharing your secrets and asking ChatGPT to solve a personal dilemma).

If using publicly available AI then you must follow the following basic rules:

- No personal data should be used in these apps or services.
- No business sensitive data should be used in these apps or services.
- These apps must only be used for non-clinical purposes.
- You must inform the Information Governance team where you intend to use these services for routine working.
- You must be aware of any copyright and intellectual property considerations when using generative AI.
- Users should be aware of any potential ethical considerations when using these products. Including the potential to propagate biased, discriminatory, or harmful content.
- Be aware that you will need to verify any output of these products to ensure accuracy.
- AI software used for work purposes should only be accessed via corporate devices.
- As per the Acceptable Use Policy you must not install any software without explicit permission from IT. Additionally downloading commercial software is not permitted without a license, in this case please refer to procuring AI products.

Nationally procured AI functions

When considering the use of nationally procured / implemented AI functions such as those within Microsoft, please consider the following:

- Is the IG team aware of such implementation and system function
- Has NHS England procured such function and is offering this to ICBs to use
- Is there any assurance documents in place associated with the AI functions e.g. a Data Protection Impact Assessment
- Are there any national guidance provided on how to use and implement such tools

When procuring and implementing artificial intelligence products or systems that include AI features you must:

- Engage with the procurement process set out within the Procurement policy.
- Engage with Digital/ Technical & Business Intelligence Teams.
- You are **legally required** to complete a Data Protection Impact Assessment (DPIA), the service area and the supplier must engage with this process.
- You must consider the risks and practical steps to reduce these risks that are documented in the ICO's AI Toolkit AI and data protection risk toolkit | ICO
- If the AI is associated with healthcare provision (such as image reading) a Digital Technology Assessment Criteria must be completed.
- As part of the DPIA and DTAC processes any associated biases or ethical concerns must be documented and addressed; potential societal impact and ethical implications of AI deployments should be carefully assessed and mitigated.
- If the AI is associated with research, you must obtain approval from the Health Research Authority (HRA).
- The Clinical Safety Officer (or their nominated representative) and the Medical Device Safety Officer - MDSO (if developing a medical device) must be consulted throughout procurement and implementation. If you require an MDSO this role will be sourced from an external organisation.
- You must adhere to the conditions set out in Article 22 of the UK General Data Protection Regulation in relation to automated individual decision making, including profiling. – Individuals have the right not to be subject to automated decision making.
- **AI outcomes or outputs must be reviewed by a human. You cannot rely solely on the use of AI for decision making, there must be substantial involvement from an appropriately qualified human.**
- There must be an agreed process to flag any concerns regarding the output of any AI products.
- If there are concerns which have led to an incident this must be reported as per the IG Incident Reporting Policy.

- Incident response plans should be established to handle security incidents, including data breaches, unauthorised access, and system failures.
- Use of AI must be transparent to staff and patients ensuring they understand where it is being used and how it may impact their employment, work or care. The logic behind it must be explainable in plain English without abbreviations or specialised terms .
- Data must be collected and processed in a lawful and ethical manner following all recommendations from
- AI and data protection risk toolkit with appropriate consent and anonymisation measures in place.
- Data access and sharing must be strictly controlled, and data must be stored securely throughout its lifecycle.
- You should conduct patient and public engagement activities that include determining if individuals support the use of data for your intended purpose, or if they have any concerns on how their data will be used.
- If the use of AI involves service change then prior to the implementation of any AI programme, formal consultation must take place with employees and their trade union representatives in accordance with the organisational change policy.
- You must be assured that any product mitigates against bias and discrimination.
- AI systems should be continuously monitored for suspicious activities, anomalies, and potential security breaches.

DO NOT ADD ANY FURTHER SECTIONS AFTER SECTION 6.0

NHS
Bedfordshire, Luton and Milton Keynes
Integrated Care Board

Appendix 1 - Equality Impact Assessment Initial Screening

Please answer the questions against each of the protected characteristic and inclusion health groups. If there are significant impacts and issues identified a full Equality / Quality Impact Assessment (EQIA) must be undertaken. It is against the law to discriminate against someone because of these protected characteristics. For support and advice on undertaking EQIAs please contact: agcsu.equalities@nhs.net

Name of Policy:	**Artificial Intelligence Policy**
Date of assessment:	07-02-25
Screening undertaken by:	Head of Safe Practice and Data Protection Officer

Protected characteristic and inclusion health groups. Find out more about the Equality Act 2010, which provides the legal framework to tackle disadvantage and discrimination: https://www.equalityhumanrights.com/en/equality-act/protected-characteristics	Could the policy create a disadvantage for some groups in application or access? No. The policy is specifically to prevent this	If Yes - are there any mechanisms already in place to mitigate the potential adverse impacts identified? If not, please detail additional actions that could help. If this is not possible, please explain why
Age A person belonging to a particular age (for example 32 year olds) or range of ages (for example 18 to 30 year olds).	No	
Disability A person has a disability if she or he has a physical or mental impairment which has a substantial and long-term adverse effect on that person's ability to carry out normal day-to-day activities.	No	
Gender reassignment The process of transitioning from one gender to another.	No	
Marriage and civil partnership Marriage is a union between a man and a woman or between a same-sex couple. Same-sex couples can also have their relationships legally recognised as 'civil partnerships'.	No	
Pregnancy and maternity Pregnancy is the condition of being pregnant or expecting a baby. Maternity refers to the	No	

period after the birth and is linked to maternity leave in the employment context. In the non-work context, protection against maternity discrimination is for 26 weeks after giving birth, and this includes treating a woman unfavourably because she is breastfeeding.		
Race Refers to the protected characteristic of race. It refers to a group of people defined by their race, colour and nationality (including citizenship) ethnic or national origins.	No	
Religion or belief Religion refers to any religion, including a lack of religion. Belief refers to any religious or philosophical belief and includes a lack of belief. Generally, a belief should affect your life choices or the way you live for it to be included in the definition.	No	
Sex A man or a woman.	No	
Sexual orientation Whether a person's sexual attraction is towards their own sex, the opposite sex, to both sexes or none.	No	
Carers Individuals within the ICB which may have carer responsibilities.	No	
Please summarise the improvements which this policy offers compared to the previous version or position.		
N/A as new policy.		
Has potential disadvantage for some groups been identified which require mitigation?		
No		

Appendix 2 - Data Protection Impact Assessment Initial Screening

Data protection is the fair and proper use of information about people. Before completing this form, please refer to the Data Protection Impact Assessment (DPIA) Guidance in the Information Governance (IG) section on the staff Intranet or contact the Data Protection Officer for support via blmkccg.ig@nhs.net

A DPIA is a process to help you identify and minimise the data protection risks. You must do a DPIA for processing that is likely to result in a high risk to individuals. You can use our screening checklist below to help you decide when to do one. If you have answered 'Yes' to any of the 10 screening questions, you must then carry out a full DPIA using the Stage 2 form, which is also available on the Intranet in the IG section.

Name of Policy:	**Artificial Intelligence Policy**
Date of assessment:	07-02-25
Screening undertaken by:	Head of Safe Practice and Data Protection Officer

Stage 1 – DPIA form **please answer 'Yes' or 'No'**

1.	**Will the policy result in the processing of personal identifiable information / data?** This includes information about living or deceased individuals, including their name, address postcode, email address, telephone number, payroll number etc.	Yes
2.	**Will the policy result in the processing of sensitive information / data?** This includes for living or deceased individuals, including their physical health, mental health, sexuality, sexual orientation, religious belief, National Insurance No., political interest etc.	Yes
3.	**Will the policy involve the sharing of identifiers which are unique to an individual or household?** e.g., Hospital Number, NHS Number, National Insurance Number, Payroll Number etc.	Yes
4.	**Will the policy result in the processing of pseudonymised information by organisations who have the key / ability to reidentify the information?** **Pseudonymised data -** where all identifiers have been removed and replaced with alternative identifiers that do not identify any individual. Re-identification can only be achieved with knowledge of the re-identification key. **Anonymised data -** data where all identifiers have been removed and data left does not identify any patients. Re-identification is remotely possible, but very unlikely.	Yes
5.	**Will the policy result in organisations or people having access to information they do not currently have access to?**	No
6.	**Will the policy result in an organisation using information it already holds or has access to, but for a different purpose?**	Yes
7.	**Does the policy result in the use of technology which might be perceived as being privacy intruding?** e.g., biometrics, facial recognition, CCTV, audio recording etc.	No
8.	**Will the policy result in decisions being made or action being taken against individuals in ways which could have a significant impact on them?** Including profiling and automated decision making. (This is automated processing of personal data to evaluate certain things about an individual i.e., diagnosis and then making a decision solely by automated means - without any human involvement)	No
9.	**Will the policy result in the collection of additional information about individuals in addition to what is already collected / held?**	No
10.	**Will the policy require individuals to be contacted in ways which they may not be aware of and may find intrusive?** e.g., personal email, text message etc.	No